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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,069	07/24/2003	Garret D. Cawthon	37013-6	9758
52450	7590	11/30/2005		
KRIEG DEVAULT LLP ONE INDIANA SQUARE SUITE 2800 INDIANAPOLIS, IN 46204-2079			EXAMINER LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/626,069	Applicant(s) CAWTHON, GARRET D.	
	Examiner Marina Lamm	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/9/05 has been entered.
2. Claims pending are 39-73. Claims 39, 58 and 59 have been amended. Claims 61-73 remain withdrawn from consideration as directed to non-elected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 58 are viewed as indefinite because they recite the limitation "a member selected from the group consisting of...calendula, chamomile..." Claim 51 is viewed as indefinite because it recites the limitation "a member selected from the group consisting of calendula, chamomile and comfrey". It is unclear whether the Applicant

intended to claim extracts of said plants, fresh plants, dried plants or essential oils of said plants or any other plant material(s).

Claims 40-50 and 52-57 are rejected as indefinite because they contain all the limitations of Claims 39 or 51, rejected for the reasons given above.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 39-50 and 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502), all of record.

a. Adams et al. in view of Moss and Mulder

Adams et al. teach diaper rash aerosol composition containing about 70% of water, jojoba oil and macadamia oil. The recitation of viscosity that is "sufficiently low to allow the composition to be atomized" is inherent in the reference because the reference teaches compositions in the form of aerosols. The Adams et al. reference does not teach the component (2) of the instant claims. However, Moss teaches that severe cases of diaper rash may result in complications such as decubitus ulcer, wherein skin breaks down. See col. 1, lines 21-27. Moss suggests that is desirable to treat diaper rash and decubitus ulcer simultaneously. See col. 1, lines 33-47. The compositions of Moss contain zinc oxide, which has antiseptic activity, and cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing.

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See col. 2, lines 48-55; col. 3, lines 35-47. Further, Mulder teaches using zinc oxide topical protectant in spray-on liquid compositions for the treatment of skin lesions (e.g. skin injury and skin tears) in order to promote healing. See col. 1, lines 15-21; col. 2, lines 42-43; Example 1. Mulder also teaches using petrolatum and lanolin as emollients in topical compositions for their soothing action by lubricating injured skin. See col. 4, lines 50-56. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. such that to use zinc oxide for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain an antiseptic and wound healing effect as suggested by Moss and Mulder. One having ordinary skill in the art would have a reasonable expectation of success because Mulder shows how to incorporate zinc oxide into spray-on liquid compositions. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. such that to use cod liver oil, lanolin and petrolatum. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing and soothing action of the composition as suggested by Moss and Mulder. With respect to Claims 41-43 and 60, which recite an average particle size of zinc oxide, neither reference explicitly teaches the claimed size. However, the determination of optimal or workable size of zinc oxide by routine experimentation is obvious absent showing of criticality of the claimed size.

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One having ordinary skill in the art would have been motivated to do this to obtain the desired skin protectant and/or aesthetic properties of the composition.

b. Gebhart et al. in view of Moss and Mulder

Gebhart et al. teach aerosol compositions for the treatment of skin irritations such as diaper rash containing sesame oil (or other plant-based oils), vitamins A and D, and other topical ingredients. See col. 1, lines 37-40; col. 6, lines 46-59; col. 7, lines 71-75; col. 8, Example 9. The compositions of Gebhart et al. form a film on the area being treated. See col. 3, lines 11-15. The recitation of viscosity that is "sufficiently low to allow the composition to be atomized" is inherent in the reference because the reference teaches compositions in the form of aerosols. Gebhart et al. do not teach the component (2) of the instant claims. However, Moss teaches that severe cases of diaper rash may result in complications such as decubitus ulcer, wherein skin breaks down. See col. 1, lines 21-27. Moss suggests that is desirable to treat diaper rash and decubitus ulcer simultaneously. See col. 1, lines 33-47. The compositions of Moss contain zinc oxide, which has antiseptic activity, and cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. Further, Mulder teaches using zinc oxide topical protectant in spray-on liquid compositions for the treatment of skin lesions (e.g. skin injury and skin tears) in order to promote healing. See col. 1, lines 15-21; col. 2, lines 42-43; Example 1. Mulder also teaches using petrolatum and lanolin as emollients in topical compositions for their soothing action by lubricating injured skin. See col. 4, lines 50-56.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. such that to use zinc oxide for its art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain an antiseptic and wound healing effect as suggested by Moss and Mulder. One having ordinary skill in the art would have a reasonable expectation of success because Mulder shows how to incorporate zinc oxide into spray-on liquid compositions. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. such that to use cod liver oil, lanolin and petrolatum. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing and soothing action of the composition as suggested by Moss and Mulder. With respect to Claims 41-43 and 60, which recite an average particle size of zinc oxide, neither reference explicitly teaches the claimed size. However, the determination of optimal or workable size of zinc oxide by routine experimentation is obvious absent showing of criticality of the claimed size. One having ordinary skill in the art would have been motivated to do this to obtain the desired and/or acceptable skin protectant and/or aesthetic (e.g. smoothness, homogeneity) properties of the composition. With respect to Claims 54-56, neither the Gebhart et al. not the Adams et al. reference explicitly teaches the claimed viscosity. However, the determination of optimal or workable viscosity by routine experimentation is obvious absent showing of criticality of the claimed viscosity. One having ordinary skill in the art

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would have been motivated to do this to obtain the desired sprayability of the composition.

7. Claims 41-43, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502), and further in view of Boussouira et al. (US 6,103,247), all of record.

Adams et al. or Gebhart et al. in view of Moss and Mulder applied as above. Neither reference explicitly teaches the zinc oxide particle size of the instant claims. However, Boussouira et al. teach using transparent zinc oxide having an average diameter of 1-500 nm in cosmetic composition because of its aesthetic appeal. See col. 5, lines 31-42. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. or Gebhart et al. in view of Moss and Mulder such that to use transparent zinc oxide having an average diameter of 1-500 nm. One having ordinary skill in the art would have been motivated to do this to obtain aesthetically pleasing compositions as suggested by Boussouira et al.

8. Claims 39, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Neubourg (WO 99/08649 as translated by US 6,423,323).

Adams et al. or Gebhart et al. applied as above. Further, Adams et al. teach using "herbs tea" in their diaper rash aerosol formulations. Neither reference teaches

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calendula, chamomile or comfrey of the instant claims. However, Neubourg teaches using calendula and chamomile extracts in topical diaper rash treatment compositions. See col. 5, lines 15-24. Chamomile is used for its soothing properties. See col. 5, lines 11-14. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. or Gebhart et al. such that to use calendula and/or chamomile extracts. One having ordinary skill in the art would have been motivated to do this to obtain soothing and diaper rash-treating properties as suggested by Neubourg.

9. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Neubourg (WO 99/08649 as translated by US 6,423,323) as applied to Claim 51 above and further in view of Moss (US 4,816,254).

Adams et al. or Gebhart et al. in view of Neubourg applied as above. Neither reference teaches the ingredients of the instant claim. However, Moss teaches compositions for the treatment of skin irritations such as diaper rash containing cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Gebhart et al. such that to use cod liver oil instead of vitamins A and D. One having ordinary skill in the art would have been motivated to do this because cod liver oil contains vitamins A and D and promotes

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rapid, scar-free healing as suggested by Moss. Alternatively, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the compositions of Adams et al. in view of Neubourg such that to use cod liver oil. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing action as suggested by Moss.

Response to Amendment & Arguments

10. The declaration under 37 CFR 1.132 filed 8/16/05 has been considered but is insufficient to overcome the rejection of claims 39-60 based upon the art of record as set forth in the last Office action because: the Applicant has not presented any experimental data in support of her opinion. Due to the absence of tests comparing Applicant's compositions with those of the closest prior art and apparent self-interest of the declarant, the declaration constitutes a self-serving opinion testimony, which is entitled to little weight. See MPEP 716.01.

11. Applicant's arguments with respect to claims 39-60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. No claim is allowed at this time.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,382,919; US 4,937,234; US 5,455,033; US 5,961,957.

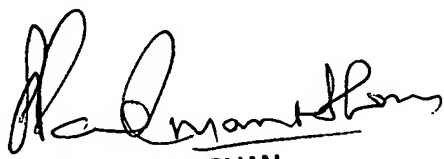
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
11/26/05


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER